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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/781,296
Filing Date: January 13, 1997
Appellent(s): HARLEY ET AL.

Steven L. Highlander
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 28 September 2006 appealing from the Office action mailed 3 February 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Chen et al. *Virology* 205:486-495 (1995).

Russell et al. *Journal of Molecular Biology* 244:332-350 (1994).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38, as recited in the instant claims. SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38, per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 27 and 29 are directed to encompass combinations of these sequences, as well as sequences larger than the recited

sequences. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Therefore, only SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Virology (1994) Vol. 205, pages 486-495). Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence GKHRGQGGSN (SEQ ID NO: 28; page 489, Figure 1(A)).

Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence QGGSNPK (SEQ ID NO: 29; page 489, Figure 1(A)).

Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence NPKFENIA (SEQ ID NO: 30; page 489, Figure 1(A)).

Claims 27 and 29 are drawn to a peptide composition **comprising** (emphasis added by examiner) a peptide molecule. Therefore, the peptide sequence within a larger sequence of Chen meets the limitations of the instant claims.

(10) Response to Argument

Arguments with Regard to 35 USC 112, First Paragraph

1. Appellants submit that "there is no basis in any written description case law, particularly in *Vas-Cath*, that would justify limiting the claims only to those particular sequences set forth in the application-in effect, a "consisting of" claim". Appellants further submit that the examiner has the initial burden of presenting a preponderance of evidence why a person skilled

in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims"

This argument is not persuasive. As has been pointed to in the non-final Office Action of 9 August 2005 and re-iterated with response to arguments in the Office Action of 3 February 2006, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. The first paragraph under 35 USC 112 clearly requires that the specification shall contain a written description of the invention.

Further, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002).

In addition, a lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

In the instant case, Appellant has failed to provide evidence that they were in possession of the recited "combinations" at the time of filing of the original disclosure. Appellant is reminded that an "Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998). Further, a patentee of a biotechnical invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other that those specifically enumerated".

Appellant has been invited to provide support that the specification as filed discloses the "combinations" of peptides as recited in claims 27 and 29. However, Applicant has failed to show support, in their response to the above recited Office Actions, by pointing in the original disclosure or the originally filed claims to the "combinations" of peptides, as recited in claims 27 and 29. Therefore, the Examiner maintains that the claims lack written description and further maintains that adequate "evidence" has been provided Appellant that there is no support for the recited combinations..

2. Appellant argues that "the present application describes a variety of peptides with varying lengths, and those of skill in the art would readily understand that these recited sequences could be included within larger peptide segments (but not longer than about 40 amino acids as recited) while still accomplishing the goals of the present invention-binding to autoantibodies. The examiner has made no effort to establish why one of skill in the art would not immediately comprehend that the sequences beyond those recited could be included, and that these sequences could be virtually ***any other peptide sequence*** imaginable" (emphasis added by Appellant).

This is not persuasive. Firstly, the recited claims are not understood to encompass only 40 amino acids or less, as is Appellants interpretation of the claim language. The claims, as recited, read "a peptide composition **comprising** a peptide molecule consisting of about forty amino acids or less and comprising a peptide sequence selected from the group consisting of...". Therefore, the claim is interpreted to encompass a peptide composition of which the 40 amino acids or less are from the group consisting of the recited peptides. In other words, a peptide **comprising** that peptide molecule of 40 amino acids or less **plus** other portions is recited. The claim is not limited to only a peptide composition "consisting of" 40 amino acids or less, as asserted by Appellant (emphasis added by examiner).

Secondly, Appellant is arguing that the recited sequences could be included within larger peptide segments while accomplishing the goals of the present invention, which is binding to autoantibodies. This is not the issue at hand. Appellant appears to be arguing enablement of the instant combinations, in that one of skill in the art would know how to use the recited peptides in combination to provide binding to autoantibodies. Appellant is reminded that the standard for

written description is separate and distinct from the enablement requirement. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); In re Curtis, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description").

However, in response, as is well know to one of skill in the art, sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule (the combinations of peptides recited in the claims), the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will have no effect, i.e. no binding. Several publications document the unpredictability of the relationship between sequence, structure, and function. See, for example, Russell et al. *Journal of Molecular Biology* (1994) Vol. 244, pages 332-350. Appellants have failed to disclose other peptides, in specific combination, that would accomplish the desired effect of binding specific autoantibodies. The Examiner maintains that the claims lack written description.

Arguments with Regard to 35 USC 102 (b)-Chen et al.

1. Appellant argues that "to the extent that the reference is said to disclose a peptide comprising SEQ ID NOS: 28-30. Careful review of FIG. (1A) of the reference, cited by the examiner as the relevant disclosure, reveals that the illustrated sequence is not a discrete peptide, but rather, is an illustrated portion of a larger protein-EBNA-I. Thus the reference fails to satisfy the recitation in claim 27 of a peptide of about 40 amino acids or less".

This is not persuasive. As is stated above, the recited claims are not understood to encompass only 40 amino acids or less, as is Appellants interpretation of the claim language. The claims, as recited, read "a peptide composition **comprising** a peptide molecule consisting of about forty amino acids or less and comprising a peptide sequence selected from the group consisting of...". Therefore, the claim is interpreted to encompass a peptide composition of which the 40 amino acids or less are from the group consisting of the recited peptides. In other words, a peptide **comprising** that peptide molecule of 40 amino acids or less **plus** other portions is recited. The claim is not limited to only a peptide composition "consisting of" 40 amino acids or less, as asserted by Appellant (emphasis added by examiner). Therefore, the teaching of Chen et al. of a peptide sequence comprising GKHRGQGGSN (SEQ ID NO: 28; page 489, Figure 1(A)), QGGSNPK (SEQ ID NO: 29; page 489, Figure 1(A)), and NPKFENIA (SEQ ID NO: 30; page 489, Figure 1(A)), read on the instantly recited claims 27 and 29. It is maintained that Chen et al. anticipate the instant claims.

Further, it is noted that the examiner has indicated to Appellant, in the Office Action of 9 August 2005, that the following sequences appear to be free of the prior art: SEQ ID NOs: 1, 2, 3, 13, 14, 17-19, 21, 23, 25-27, 29, 31-33, 38, and 38.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Lori A. Clow, Ph.D.

Patent Examiner

Conferees:

James Douglas Schultz, Ph.D.

JAMES SCHULTZ, PH.D.
Supervisory PRIMARY EXAMINER

Irem Yucel, Ph.D.

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600